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510(K) SUMMARY
for
InterDry

1. SPONSOR

Milliken Healthcare Products, LLC
920 Milliken Road
Spartanburg, SC 29303
Telephone: 864-503-1323
Facsimile: 864-504-6800

Primary Contact: Brian J Lindsay (864-503-1323)
Secondary Contact: Peter Kang (864-503-6452)

Date Prepared: March 11, 2011

2. DEVICE NAME

Proprietary Name:	InterDry
Common/Usual Name:	Skin Protectant
Classification Name:	Fiber, Medical, Absorbent (21 CFR 880.5300, Product Code FRL)

3. PREDICATE DEVICE

- InterDry Textile with Silver (K061615, Milliken Healthcare Products, LLC)
- SurePress Absorbent Padding (21 CFR 880.5300, Convatec, Inc.)

4. DEVICE DESCRIPTION

InterDry is a non-sterile skin protectant fabric with an antimicrobial silver complex. InterDry is a single patient use product that is custom cut from a multiuse package.

5. INDICATIONS FOR USE

InterDry is a skin protectant indicated for management of skin folds and other skin-to-skin contact areas. InterDry reduces microbial colonization in the fabric.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The InterDry is identical to the previously cleared InterDry Textile with Silver (K061615).

The technological characteristics of InterDry and the predicate products are substantially equivalent in that they are devices designed for moisture (fluid) absorption and are suitable for use on skin.

InterDry is substantially equivalent in material, design, performance and indications for use to the original InterDry Textile with Silver (K061615), which is indicated for prescription use only. The InterDry is substantially equivalent in design, function and intended use to the SurePress™ Absorbent Padding from ConvaTec which is indicated for over-the-counter use.

7. PERFORMANCE TESTING

Biocompatibility testing was performed in accordance with the International Organization for Standardization recommendations. Results of the biocompatibility tests demonstrate that the device is suitable for its intended use.

Antimicrobial effectiveness testing was performed which showed that InterDry reduces microbial colonization within the device itself.

Physical property testing was performed, including absorption, wicking, friction and silver release. Results of the physical testing indicate that the physical properties of the InterDry are substantially equivalent to the SurePress Absorbent Padding and that the InterDry is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV - 4 2011

Mr. Brian J. Lindsay
Quality & Regulatory Manager
Milliken Healthcare Products, LLC
920 Milliken Road
Spartanburg, South Carolina 29303

Re: K110715
Trade/Device Name: InterDry
Regulation Number: 21 CFR 880.5300
Regulation Name: Medical Absorbent Fiber
Regulatory Class: I
Product Code: FRL
Dated: May 19, 2011
Received: June 3, 2011

Dear Mr. Lindsay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110715

Indications for Use

510(k) Number (if known): K110715

Device Name: InterDry

Indications for Use:

InterDry Textile is a skin protectant indicated for management of skin folds and other skin-to-skin contact areas. InterDry Textile reduces microbial colonization in the fabric.

Prescription Use _____ AND/OR Over-the-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/3/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110715